Diploma e Master Universitario in Alti Studi Europei
Collegio Europeo di Parma

Seminar on:
"EU Pharmaceutical Policy"
2017

Presentation by Prof. Deboyser

A) Historic perspective
1) From the early years to thalidomide
2) From 1965 to 1985
3) A single market for pharmaceuticals

B) Notions
1) Definition of medicinal product
2) Prescription only v. OTC
3) Herbal medicines, homeopathic medicines and food supplements

C) Application for marketing authorization
1) Notice to applicants
2) Testing and clinical trials
2) Abridged applications

D) Marketing authorisation
1) Criteria for authorization
2) Procedures
3) Maintenance, suspension, revision

E) Control on manufacture and quality
1) Manufacturing authorization
2) Good manufacturing practices
3) Inspections and MRAs

F) Pharmacovigilance
1) Principles
2) Recent EU legislation
3) "Mediator"

G) The European Medicines Agency (EMA)
1) Mission and organization
2) A network agency
3) Comparison with EFSA

H) The protection of pharmaceutical innovation

1) Pharmaceutical patents
2) Complementary protection certificate
3) Protection of the first applicant (data exclusivity)

K) Orphan medicinal products

1) Rare diseases
2) Regulation (EC) No 141/2000
3) Market exclusivity / pricing

I) Generic competition

1) Market access for generic products
2) Generic substitution
3) Biosimilars

J) Cross-border sales

1) Parallel imports
2) Personal imports
3) Internet sales